UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/719,946	12/15/00	JOMAA H	12964.19

HM12/0517

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EXAMINER	
KWON, B	
ART UNIT	PAPER NUMBER
1614	6

DATE MAILED: 05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/719,946	JOMAA, HASSAN	
	Examiner	Art Unit	
	Brian-Yong S Kwon	1614	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Title of the Invention

1. Title of the invention is too long. The following title is suggested: " Use of Medicaments Containing Bisphosphonic Acids and Derivatives Thereof".

2. The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a).

Specification

3. If applicant desires priority under 35 U.S.C. 120 of a national stage application filed under 35 U.S.C 371, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. Appropriate correction is required.

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. Word "to" is missing after "due" in page 1, line 21 of the instant specification. Appropriate correction is required.

Claim Objections

6. Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

7. It is noted that applicant has presented the claim 4 in improper format. If applicant intends to incorporate various diseases or conditions into a method claim, applicant is advised to amend the claim in proper Markush format. Furthermore, if applicant intends to incorporate various antigens or allergens into the method claim, applicant should rewrite the claim in dependent form to incorporate such limitations. Appropriate correction is required. See 37 CFR 1.75.

8. Claim 2 is objected to because of the following informalities: Spelling of "residue" appears to be missing of word "- - -idue" in page 3, line 16; and spelling of "vulgaris" appears to be missing of word "vu - - - ris" in page 5, line 16. Appropriate correction is required.

9. Applicant is strongly advised to amend claims 1-5 conforming with current U.S. practice such that claiming subject matters in claims 1-5 are clearly presented for the prosecution of instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific substituents for R2 does not reasonably provide enablement for the term "functional group". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404* where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman, 230 USPQ 546 (BdApls) at 547* the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define those characteristics defining a "functional group". In the instant case, applicant fails to set forth limitation regards to what is "functional group" of R2. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on any "substituents", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

11. Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific autoantigens or the specific allergens, does not reasonably provide enablement for the term "autoantigens" or "allergens". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Although the specification recites examples of autoantigens or allergens (in page 10 and 11), the term "autoantigens" or "allergens" without limitations is interpreted as any substance that trigger the immune system. The specification is insufficient to enable one skilled in the art to practice the invention without undue amount of experimentation. . The breadth of claims encompasses any substances having any immunological effects which can not be determined by ordinary skill in the art. Applicant fails to provide information allowing the skilled artisan to ascertain "autoantigens" or "allgergens" without undue experimentation. The instant claims 3 and 7 read on any substances that trigger the immune system, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Thus, Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 provide for the use of bisphosphonic acids and the derivatives thereof, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

13. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite by reciting "characterised in that", "may be..." and "may mean". Claim 1 is generally narrative and indefinite, failing to conform with current U.S. practice. Claim 1 appears to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors.

Claim 1 recites the limitation "the specific autoantigens", " the particular allergy", "the specific allergens", "the particular autoantigens or allergens", "the analogues", "the mentioned

substances" and "the corresponding whole molecule" in line 18, 21, 22, 23, 25, 28 and 29 respectively. Also, applicant is requested to clarify what does it mean by "the specific autoantigens", " the particular allergy", "the specific allergens", "the particular autoantigens or allergens", "the mentioned substances" and "the corresponding whole molecule".

Regarding claims 1-3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 4 is vague and indefinite by reciting "further extracts from nervous system tissue". It is not clear what does applicant mean by "further extracts from nervous system tissue" and applicant is requested to clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawabe et al. (WO 9305052) in view of Michael et al. (US 6174529 B1).

Claims read use of bisphosphonic acids and the derivatives represented by general formula in claim 1 for treatment of autoimmune diseases or allergies in combination with autoantigens or allergens.

Kawabe et al. teach the use of methanediphosphonic acid derivative for treating autoimmune disease, rheumatisam, and etc...

Michael et al. teach the use of protein antigen (i.e., myelin basic protein, acetyl choline receptor or type II collagen, insulin, thyroid protein, etc...) or allergens (i.e., ragweed, rye, junegrass, sagebrush, etc..., see from column 2 line 59 to column 3 line 52) for treating autoimmune disease and allergy.

The teaching of Kawabe et al. differs from the claimed invention in the combination use of bisphosphonic acids and the derivatives in combination with autoantigens or allergens for the treatment of autoimmune disease and allergy. To incorporate such teaching into the teaching of Kawabe et al., would have been obvious in view of Michael et al. who teach the use of protein antigen (i.e., myelin basic protein, acetyl choline receptor or type II collagen, insulin, thyroid protein, etc...) or allergens (i.e., ragweed, rye, junegrass, sagebrush, etc..., see from column 2 line 59 to column 3 line 52) for treating autoimmune disease and allergy.

The above references in combination make clear that bisphophonic acids and derivatives and protein antigens or allergens have been individually used for the treatment of autoimmune disease and/or allergy (i.e., multiple sclerosis, myasthenia gravis, rheumatoid arthritis, diabetes mellitius, autoimmune thyroiditis, hemolytic anemia, etc...). It is obvious to combine two

compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-5 are properly rejected under 35 U.S.C. 103.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mariann Cintins, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600